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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/243,008	02/02/99	SEED B	00786/270002

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EXAMINER
NOLAN, P

ART UNIT	PAPER NUMBER
1644	8

DATE MAILED: 11/16/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

09/243,008

Applicant(s)

Seed et al.

Examiner

NOLAN

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 10-4-99
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 44-47, 51-52, 56-57, 60-64, 70, 72-75, 77, 79-82 and 92-100 is/are pending in the application.
- Of the above claim(s) 56, 57, 60-64, 70, 77, 80-82, 92-99 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 44-47, 51-52, 72-75, 79 and 100 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_.

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 315
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

**Part III DETAILED ACTION**

1. This application is a continuation of 08/394,176 which is continuation-in-part of 08/203,866 which is a continuation of 07/847,566 which is continuation-in-part of 07/665,961.

2. The specification on page 1 should be amended to reflect the status of the parent application, serial number 08/394,176.

3. Claims 44-47, 51-52, 56-57, 60-64, 70, 72-75, 77, 79-82 and 92-100 are pending.

4. Applicant's election without traverse of Group I, species CD4 as the singular extracellular domain in both receptors and a TCR zeta transmembrane domain for the first chimeric receptor in Paper No. 6 is acknowledged. The cell being examined in this case is a cell with two chimeric receptors, both of which receptors have CD4 as there singular extracellular domain, TCR zeta transmembrane domain for the first chimeric receptor and an intracellular domain made up of CD28 for the second receptor.

Accordingly, claims 56-57, 60-64, 70, 77, 80-82 and 92-99 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

5. Claims 44-47, 51-52, 72-75, 79 and 100 may not have the benefit under 35 USC § 120 of the parent filing dates (2/28/94, 3/06/92, and 3/07/91), because the claimed chimeric receptors, specifically an intracellular CD28 portion, are not disclosed in the parent applications, serial numbers 08/203,866, 07/847,566 and 07/665,961.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

6. Claims 44-47, 51-52, 72-75, 79 and 100 are rejected under 35 U.S.C. § 103 as being unpatentable over US Patent No. 5,359,046 (A), in view of Harding et al. (W) Schwartz et al. (X) and Romeo et al. (IE).

The '046 patent teaches the making of chimeric receptor proteins (column 9-11, in particular) and the use of chimeric receptor proteins to activate cytotoxic T lymphocytes to kill virally infected cells or neoplastic cells (column 11, ln 47-68, in particular). In addition the '046 patent also teaches a chimeric receptor made from residues 1-370 of the mature CD4 protein (i.e. 1-369 of SEQ ID NO:1 of the instant application) as an extracellular domain useful in treating HIV infected cells, since it is well known in the art that CD4 is bound by gp120 of HIV, and residues 31-142 of the mature zeta chain (i.e. residues 421-532 of SEQ ID NO: 6 of the instant application) as an intracellular domain (column 21, ln 61-65, in particular) useful in activating cytotoxic T cells. Furthermore, the '046 patent teaches T cell chimeric receptors are used in escaping MHC restriction and allowing for the design of chimeric receptors which are useful in modulating cellular responses in providing for the use of ligands other than the normal ligand to transduce a desired signal.

The claimed invention differs from the prior art teachings only by the recitation of a second chimeric receptor with CD28 as an intracellular domain. However, Romeo et al. (IE), teach the design and use of a chimeric receptor with CD28 as an intracellular domain for use in T cell activation studies (Figure 7, in particular). Harding et al. (W), teach that CD8+ T cell (i.e. cytotoxic T lymphocytes) activation requires two signals: an antigen specific signal mediated by the T cell receptor, and an additional antigen non-specific signal provided via a CD28-B7 interaction (Summary, in particular). Schwartz (X) teaches CD28 is necessary for IL2 production, which is required for the generation of a CTL capable of lysing a target or tumor cell (Figure 2, in particular).

Therefore it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to be motivated to make a cytotoxic T lymphocyte with two chimeric receptors, both with CD4 as an extracellular domain, one with the intracellular zeta chain of a TCR and the other with a CD28 intracellular chain, with the expectation that CTL generation requires both intracellular CD28 and the TCR zeta chain.

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can

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normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

9. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

*Patrick J. Nolan*

Patrick J. Nolan, Ph.D.  
Patent Examiner, Group 1640  
November 15, 1999